

WHAT IS CLAIMED IS:

- 1 1. A system for clinical trial simulation, comprising:
 - 2 an interface having a fixed form module and a free form module, the
 - 3 interface configured to receive information that describes a trial protocol for a
 - 4 clinical trial simulation;
 - 5 a translator having a protocol parser and a code generator, the protocol
 - 6 parser configured to parse the trial protocol, the code generator configured to
 - 7 generate source code in a general purpose programming language;
 - 8 a compiler having a code parser and a machine code generator, the
 - 9 compiler configured to compile the generated source code into an executable
 - 10 program; and
 - 11 a controller communicatively coupled with the interface, the translator,
 - 12 and the compiler, the controller configured to run the executable program.
- 1 2. The system of claim 1, wherein the fixed form module is configured to receive
- 2 trial protocol information conforming to a structured format.
- 1 3. The system of claim 2, wherein the free form module is configured to receive trial
- 2 protocol information conforming to a trial design language.
- 1 4. The system of claim 1, wherein the trial protocol comprises a plurality of
- 2 schedules.
- 1 5. The system of claim 4, wherein the plurality of schedules comprises a dosing
- 2 schedule.
- 1 6. The system of claim 4, wherein the plurality of schedules comprises an
- 2 observation schedule.
- 1 7. The system of claim 6, wherein the executable program comprises a plurality of
- 2 programmable state machines.

1 8. The system of claim 7, wherein each state machine corresponds to a discrete one
2 of the plurality of schedules.

- 1 9. A method for clinical trial simulation, comprising:
 - 2 receiving trial protocol information that describes a clinical trial
 - 3 simulation;
 - 4 arranging the trial protocol information into a plurality of schedules;
 - 5 translating the plurality of schedules into a general purpose, high level
 - 6 programming language;
 - 7 compiling the translated plurality of schedules into an executable program;
 - 8 and
 - 9 executing the program as part of the clinical trial simulation.

1 10. The method of claim 9, wherein the receiving step comprises:
2 receiving trial protocol information that conforms to a structured format;
3 and
4 receiving trial protocol information that conforms to a trial design
5 language.

1 11. The method of claim 9, wherein the plurality of schedules comprises a dosing
2 schedule.

1 13. The method of claim 9, wherein the executable program comprises a plurality of
2 state machines, each state machine corresponding to a discrete one of the plurality
3 of schedules.

- 1 14. A computer readable medium having stored thereon one or more sequences of
2 instructions for causing one or more microprocessors to perform the steps for
3 simulating a clinical trial, the steps comprising:
4 receiving trial protocol information that describes a clinical trial
5 simulation;
6 arranging the trial protocol information into a plurality of schedules;
7 translating the plurality of schedules into a general purpose, high level
8 programming language;
9 compiling the translated plurality of schedules into an executable program;
10 and
11 executing the program as part of the clinical trial simulation.
- 1 15. The computer readable medium of claim 14, wherein the receiving step
2 comprises:
3 receiving trial protocol information that conforms to a structured format;
4 and
5 receiving trial protocol information that conforms to a trial design
6 language.
- 1 16. The computer readable medium of claim 14, wherein the plurality of schedules
2 comprises a dosing schedule.
- 1 17. The computer readable medium of claim 14, wherein the plurality of schedules
2 comprises an observation schedule.
- 1 18. The computer readable medium of claim 14, wherein the executable program
2 comprises a plurality of state machines, each state machine corresponding to a
3 discrete one of the plurality of schedules.

- 1 19. A system comprising a microprocessor, a persistent storage area, a volatile
2 storage area and a communication means, the system including an execution area
3 configured to simulate a clinical trial by performing the following steps:
4 receiving trial protocol information that describes a clinical trial
5 simulation;
6 arranging the trial protocol information into a plurality of schedules, the
7 plurality of schedules comprising a dosing schedule and an observation schedule;
8 translating each of the plurality of schedules into a general purpose, high
9 level programming language;
10 compiling the translated schedules into an executable program, the
11 executable program comprising a plurality of programmable state machines, each
12 state machine corresponding to a discrete one of the plurality of schedules; and
13 executing the program as part of the clinical trial simulation.

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